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EXAMINER	
KOPPIKAR, VIVEK D	
ART UNIT	**PAPER NUMBER**
3686	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/078,042	ROE ET AL.	
	Examiner	Art Unit	
	VIVEK D. KOPPIKAR	3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 14-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 14-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

1. Claims 1-10 and 14-30 have been examined in this application. This communication is a Final Office Action in response to the Amendment and Remarks filed on September 29, 2009.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 9, 10, 14-20, 25-26 and 30 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. These claims are directed towards a method for improving the health of an individual but these claims do not recite a device (e.g. a computer) which is used for carrying out the method. Therefore, these claims are not tied to a statutory class of invention. In order to overcome this rejection, the Office recommends amending the claims so that they recite a device (e.g. a computer) which is used in carrying out the claimed method. The applicants are reminded, however, that any amendment(s) to the claim(s) must have support in the specification as it was originally filed.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-2, 5, 9-10 and 14-20 rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Number 6, 319, 199 to Sheehan in view of US Patent Number 6,055,506 to Frasca, Jr. and in even further view of US Patent Number 5,828,751 to Walker and in even further view of US Patent Number 6,093,146 to Filangeri and in even further view of US Patent Number 5,291,400 to Gilham and in even further view of US Patent Number 6,283,923 to Finkelstein.

(A) As per claim 1, a system to improve the management of an individual's health (Sheehan: Abstract), the system including:

a) a data measurement mechanism generating data relevant to a particular health condition of the individual (Sheehan: Figure 1 and Col. 2, Ln. 22-33);

b) a data acquisition mechanism transferring the data relevant to a particular health condition from the data measurement mechanism to a storage medium (Sheehan: Col. 2, Ln. 34-46);

d) an information presentation mechanism displaying the information pertaining to the physical health of an individual (Sheehan: Col. 4, Ln. 54-67).

Sheehan does not teach the following feature which is taught by Frasca, Jr.:

c) at least one data analysis mechanism generating information pertaining to the health of an individual wherein the data analysis mechanism performs at least one analysis selected from the group consisting of statistical control chart techniques based on the historical or recent health data of the individual, multi-variate analysis, attribute data analysis, and reliability engineering analysis (Frasca, Jr.: Col. 8, Ln. 42-51). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the teachings of Sheehan with the aforementioned teachings from Frasca with the motivation of having a means to generate a

message (alert) if a parameter falls outside a clinical (i.e. population comparison) range as recited in Frasca, Jr. (Col. 3, Ln. 21-26).

Sheehan in view of Frasca, Jr. do not explicitly teach that the data acquisition mechanism and the data measurement mechanism are disposed on a single handheld device, however, this feature is well known in the art as illustrated by Walker (Col. 10, Ln. 47-55). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the combined teachings of Sheehan in view of Frasca, Jr. with the aforementioned teachings from Walker with the motivation of providing a means of handheld data measurement and certification as recited in Walker (Col. 10, Ln. 47-55).

The above mentioned references d not teach the following feature which is taught by Filangeri (Col. 3, Ln. 45-55 and Col. 7, Ln. 7-26):

wherein the analysis is based on historical or recent health data of the individual collected in accordance with a sampling strategy.

At the time of the invention, it would have been obvious for one or ordinary skill in the art to have modified the above mentioned references with these aforementioned features from with the motivation of having a means of being able to produce a faster diagnosis and a quicker response in emergencies, as recited in Filangeri (Col. 1, Ln. 44-49).

Sheehan in view of Frasca, Jr. in view of Walker in view of Filangeri do not teach the following feature which is taught by Gilham (Col. 1, Ln. 24-32):

(a sampling strategy of) collecting (or the collection) of the data (for patients) on a plurality of days.

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the combined teachings of Sheehan in view of Frasca, Jr. in view of Walker in view of Filangeri with these aforementioned teachings from Gilham with the motivation of having a means of collecting as much data as possible in order to get a statistical data profile of a patient that represents (approximates) a patient's typical day, as recited in Gilham (Col. 1, Ln. 24-32).

The above-aforementioned references do not teach the following features which is taught by Finkelstein (Col. 3, Ln. 44-65):

wherein the data measurement mechanism generates data relevant to the individual's asthmatic condition.

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the above, aforementioned references with these teachings from Finkelstein with the motivation of having an enhanced and improved means of monitoring the severity of asthma in various patients, as recited in Finkelstein (Col. 3, Ln. 1-20).

As per claims 21-22, Frasca, Jr. teaches that the analysis comprises statistical chart control techniques and wherein the analysis comprises multi-variate analysis of variable and attribute data (Frasca: Col. 8, Ln. 42-51 and Col. 14, Ln. 15-33). The motivation for making this modification to the teachings of Frasca, Jr. is the same as that set forth above.

(B) As per claim 2, in the system of Sheehan in view of Frasca, Jr. in view of Walker in view of Filangeri the at least one data analysis mechanism further comprises data analysis software (Sheehan: Col. 2, Ln. 58-62 and Col. 7, Ln. 47-59).

(C) As per claim 5, in the system of Sheehan in view of Frasca, Jr. in view of Walker in view of Filangeri the at least one data measurement mechanism includes a sensor (Sheehan: Col. 1, Ln. 29-38).

(D) As per claim 9, Sheehan in view of Frasca, Jr. in view of Filangeri in view of Gilham teach a method for improving the health of an individual (Sheehan: Abstract) including the steps of:

a) selecting at least one health parameter appropriate for the individual based on the individual's medical condition and medical history, current or recent health event(s) of interest, age and/or demographics, or any other health parameter of interest to the individual, caregiver, or medical professional (Sheehan: Col. 4, Ln. 12-18);

b) measuring the at least one health parameter of interest and pertinent environmental or qualitative information to produce data (Sheehan: Col. 2, Ln. 23-46);

c) acquiring the data for storage and subsequent analysis (Sheehan: Col. 2, Ln. 23-46); and

e) presenting the information (alert) to the individual, caregiver, or medical professional (Sheehan: Col. 6, Ln. 47-59 and Col. 7, Ln. 13-19).

Sheehan does not teach the following feature which is taught by Frasca, Jr.:

d) analyzing the data via at least one data analysis mechanism to define at least one of an out-of-control situation requiring intervention and/or potential causes or remedies of an out-of-control situation wherein the data analysis mechanism performs at least one analysis selected from the group consisting of statistical control chart techniques, multi-variate analysis, attribute data analysis, and reliability engineering analysis (Frasca: Col.8, Ln. 42-51). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the

teachings of Sheehan with the aforementioned teachings from Frasca with the motivation of having a means to generate a message (alert) if a parameter falls outside a clinical (i.e. population comparison) range as recited in Frasca, Jr. (Col. 3, Ln. 21-26).

The above mentioned references d not teach the following feature which is taught by Filangeri (Col. 3, Ln. 45-55 and Col. 7, Ln. 7-26):

creating a sampling strategy for measuring the at least one health parameter of interest based on the historical or recent health data of the individual and measuring data according to the sampling strategy.

At the time of the invention, it would have been obvious for one or ordinary skill in the art to have modified the above mentioned references with these aforementioned features from with the motivation of having a means of being able to produce a faster diagnosis and a quicker response in emergencies, as recited in Filangeri (Col. 1, Ln. 44-49).

Sheehan in view of Frasca, Jr. in view of Filangeri do not teach the following feature which is taught by Gilham (Col. 1, Ln. 24-32):

(a sampling strategy of) collecting (or the collection) of the data (for patients) on a plurality of days.

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the combined teachings of Sheehan in view of Frasca, Jr. in view of Filangeri with these aforementioned teachings from Gilham with the motivation of having a means of collecting as much data as possible in order to get a statistical data profile of a patient that represents (approximates) a patient's typical day, as recited in Gilham (Col. 1, Ln. 24-32).

The above-aforementioned references do not teach the following features which is taught by Finkelstein (Col. 3, Ln. 44-65):

wherein the data measurement mechanism generates data relevant to the individual's asthmatic condition.

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the above, aforementioned references with these teachings from Finkelstein with the motivation of having an enhanced and improved means of monitoring the severity of asthma in various patients, as recited in Finkelstein (Col. 3, Ln. 1-20).

As per claim 25-26, Frasca, Jr. teaches that the analysis comprises statistical chart control techniques and wherein the analysis comprises multi-variate analysis of variable and attribute data (Frasca: Col. 8, Ln. 42-51 and Col. 14, Ln. 15-33). The motivation for making this modification to the teachings of Frasca, Jr. is the same as that set forth above.

(E) As per claims 14-20 and 26-30, these claims are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheehan in view of Frasca, Jr. in view of Filangeri in view of Gilham, as applied to Claim 9, and in even further view of Official Notice.

As per claims 14-20 and 27-30, the Office takes the position that the recited steps are steps which are well known in the art for analyzing data using statistics and therefore the Office takes Official Notice with regard to these features. At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the combined teachings of Sheehan in view of Frasca, Jr. in view of Gilham with these steps with the motivation of having a systematic means of analyzing the data and determining outliers (the outliers are determined in part by having target or base values) in the data set so that the patients (individuals) who

represented these outliers could be alerted of their potentially out-of-control situation (e.g. health condition).

(F) As per claim 10, in the method of Sheehan the information presented is selected from the group: statistical analysis, out-of-control points, control rules violations, specification violations, medical limit violations, medical condition related information, advertising for products related to the individual's medical condition or health event, help guides, summary screens (Sheehan: Figures 3 and 5 (220); Col. 4, Ln. 62-68 and Col. 7, Ln. 4-18).

6. Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheehan in view of Frasca, Jr. in view of Walker in view of Filangeri and in even further view of US Patent Number 6,658,287 to Litt and in even further view of Gilham and in even further view of US Patent Number 6,283,923 to Finkelstein.

(A) As per claim 6, Sheehan in view of Frasca, Jr. in view of Walker in view of Litt teaches a system to improve the management of an individual's health (Sheehan: Abstract), the system including:

a) a data measurement mechanism generating data relevant to a particular health condition (Sheehan: Figure 1 and Col. 2, Ln. 22-33);

b) at least one data acquisition mechanism transferring the data from the data measurement mechanism to a storage medium wherein the at least one data acquisition mechanism is selected from the group consisting of : a tablet PC, voice recognition, and telemetry based systems (Sheehan: Col. 2, Ln. 34-46 and Col. 8, Ln. 18-32);

d) an information presentation mechanism displaying the information pertaining to the health of an individual (Sheehan: Figures 3 and 5 (220) and Col. 4, Ln. 54-67);

Sheehan does not teach the following feature which is taught by Frasca, Jr.:

c) at least one data analysis mechanism generating information pertaining to the health of an individual (Frasca: Col. 8, Ln. 42-51). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the teachings of Sheehan with the aforementioned teachings from Frasca with the motivation of having a means to generate a message (alert) if a parameter falls outside a clinical (i.e. population comparison) range as recited in Frasca, Jr. (Col. 3, Ln. 21-26).

Sheehan in view of Frasca, Jr. do not explicitly teach a handheld data measurement mechanism, however, this feature is well known in the art as illustrated by Walker (Col. 10, Ln. 47-55). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the combined teachings of Sheehan in view of Frasca, Jr. with the aforementioned teachings from Walker with the motivation of providing a means of handheld data measurement and certification as recited in Walker (Col. 10, Ln. 47-55).

Sheehan in view of Frasca, Jr. in view of Walker do not teach or suggest that the displayed information comprises a statistical control chart based on the historical or recent health data of the individual, however, this feature is well known in the art as illustrated by Litt (Col. 13, Ln. 18-41). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have modified the combined teachings of Sheehan in view of Frasca, Jr. in view of Walker with the aforementioned teachings from Litt with the motivation of having a means of making predictions, as recited in Litt (Col. 1, Ln. 10-18).

The above mentioned references d not teach the following feature which is taught by Filangeri (Col. 3, Ln. 45-55 and Col. 7, Ln. 7-26):

wherein the data analysis mechanism performs at least one statistical control chart analysis based on historical or recent health data of the individual collected in accordance with a sampling strategy.

At the time of the invention, it would have been obvious for one or ordinary skill in the art to have modified the above mentioned references with these aforementioned features from with the motivation of having a means of being able to produce a faster diagnosis and a quicker response in emergencies, as recited in Filangeri (Col. 1, Ln. 44-49).

Sheehan in view of Frasca, Jr. in view of Filangeri do not teach the following feature which is taught by Gilham (Col. 1, Ln. 24-32):

(a sampling strategy of) collecting (or the collection) of the data (for patients) on a plurality of days.

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the combined teachings of Sheehan in view of Frasca, Jr. in view of Filangeri with these aforementioned teachings from Gilham with the motivation of having a means of collecting as much data as possible in order to get a statistical data profile of a patient that represents (approximates) a patient's typical day, as recited in Gilham (Col. 1, Ln. 24-32). The above-aforementioned references do not teach the following features which is taught by Finkelstein (Col. 3, Ln. 44-65):

wherein the data measurement mechanism generates data relevant to the individual's asthmatic condition.

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the above, aforementioned references with these teachings from Finkelstein

with the motivation of having an enhanced and improved means of monitoring the severity of asthma in various patients, as recited in Finkelstein (Col. 3, Ln. 1-20).

As per claim 23, Frasca, Jr. teaches wherein the analysis comprises multi-variate analysis of variable and attribute data (Frasca: Col. 8, Ln. 42-51 and Col. 14, Ln. 15-33). The motivation for making this modification to the teachings of Frasca, Jr. is the same as that set forth above.

(B) As per claim 7, in the system of Sheehan in view of Frasca, Jr. in view of Walker in view of Filangeri at least one data acquisition mechanism includes a handheld device selected from the group: a PDA and a handheld PC (Sheehan: Figures 3-5 and Col. 8, Ln. 18-32).

7. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sheehan in view of Frasca in view of Walker in view of Filangeri and in further view of US Patent Number 5,464,102 to Falcone and in even further view of US Patent Number 6,540,674 to Zadrozny and in even further view of Gilham and in even further view of US Patent Number 6,283,923 to Finkelstein.

(A) As per claim 8, the system of Sheehan in view of Frasca, Jr. includes:

a) a data measurement mechanism generating data relevant to a particular health condition of the individual (Sheehan: Figure 1 and Col. 2, Ln. 22-33);

b) at least one data acquisition mechanism transferring the data from the data measurement mechanism to a storage medium (Sheehan: Col. 2, Ln. 34-46);

d) an information presentation mechanism displaying to the individual the information pertaining to the health of an individual, wherein the at least one information presentation mechanism is selected from the group: a graphical summary screen, an icon based summary

screen, a help guide, an anthropomorphic help guide, and synthesized speech (Sheehan: Figures 3-5; Col. 4, 54-67 and Col. 6, Ln. 47-59).

Sheehan does not teach the following feature which is taught by Frasca, Jr.:

c) at least one data analysis mechanism generating insights relevant to a particular health condition (Frasca: Col.8, Ln. 42-51). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the teachings of Sheehan with the aforementioned teachings from Frasca with the motivation of having a means to generate a message (alert) if a parameter falls outside a clinical (i.e. population comparison) range as recited in Frasca, Jr. (Col. 3, Ln. 21-26).

Sheehan in view of Frasca, Jr. in view of Filangeri in view of Walker do not teach that the data acquisition mechanism is adapted to perform a preliminary analysis on the data and provide an output (e.g. an alarm) when the data comprises a value that is outside of a target, however, this feature is taught by Falcone (Col. 2, Ln. 9-18 and Col. 4, Ln. 22-25). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the combined teachings of Sheehan in view of Frasca with the aforementioned teachings from Falcone with the motivation of having a detection means whenever a patient's state was altered, as recited in Falcone (Col. 1, Ln. 5-10).

Sheehan in view of Frasca, Jr. in view of Walker in view of Filangeri Falcone do not teach that the information includes at least one level of intervention (i.e. recommendation) when an out-of-control condition requiring intervention has been measured, however, this feature is taught by Zadrozny (Col. 2, Ln. 33-38 and Col. 10, Ln. 28-32). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the combined

teachings of Sheehan in view of Frasca, Jr. in view of Falcone with the aforementioned teachings from Zadrozny with the motivation of having a means of recognizing events which pose a danger to ill persons and providing assistance to these ill persons, as recited in Zadrozny (Col. 2, Ln. 4-9).

The above mentioned references d not teach the following feature which is taught by Filangeri (Col. 3, Ln. 45-55 and Col. 7, Ln. 7-26):

wherein the data analysis mechanism performs at least one statistical control chart analysis based on historical or recent health data of the individual collected in accordance with a sampling strategy

At the time of the invention, it would have been obvious for one or ordinary skill in the art to have modified the above mentioned references with these aforementioned features from with the motivation of having a means of being able to produce a faster diagnosis and a quicker response in emergencies, as recited in Filangeri (Col. 1, Ln. 44-49).

The above mentioned references do not teach the following feature which is taught by Gilham (Col. 1, Ln. 24-32):

(a sampling strategy of) collecting (or the collection) of the data (for patients) on a plurality of days.

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the combined teachings of Sheehan in view of Frasca, Jr. in view of Filangeri with these aforementioned teachings from Gilham with the motivation of having a means of collecting as much data as possible in order to get a statistical data profile of a patient that represents (approximates) a patient's typical day, as recited in Gilham (Col. 1, Ln. 24-32).

The above-aforementioned references do not teach the following features which is taught by Finkelstein (Col. 3, Ln. 44-65):

wherein the data measurement mechanism generates data relevant to the individual's asthmatic condition.

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the above, aforementioned references with these teachings from Finkelstein with the motivation of having an enhanced and improved means of monitoring the severity of asthma in various patients, as recited in Finkelstein (Col. 3, Ln. 1-20).

As per claim 24, Frasca, Jr. teaches comprises multi-variate analysis of variable and attribute data (Frasca: Col. 8, Ln. 42-51 and Col. 14, Ln. 15-33). The motivation for making this modification to the teachings of Frasca, Jr. is the same as that set forth above.

8. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sheehan in view of Frasca, Jr. in view of Walker in view of Filangeri in view of Gilham in view of Finkelstein, as applied to Claim 1, above, and in further view of US Patent Number 5,920,478 to Ekblad.

(A) As per claim 3, Sheehan does not teach that the at least one data analysis mechanism further comprises automatic or triggered recalculation of control limits based on top demonstrated historical performance, however, this feature is taught by Ekblad (Col. 11, Ln. 52-59). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the system of Sheehan with the aforementioned feature from Ekblad with the motivation of having a means of allowing adaptive updating in response to changes (variations) in data, as recited in Ekblad (Col. 11, Ln. 52-59). In the alternative, the examiner takes Official Notice that this feature is well known in the art and at the time of the invention one of ordinary

skill in the art would have been motivated to have modified the system of Sheehan with this aforementioned feature with the motivation of having a means to set the control limits so that they reflected and were up to date to changes in the raw historical performance data that was obtained from various patients.

9. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sheehan in view of Frasca, Jr. in view of Walker in view of Filangeri in view of Gilham in view of Finkelstein, as applied to Claim 1, above, and in further view of US Patent Number 6,642,592 to Loman.

(A) As per claim 4, Sheehan does not teach that the reliability engineering analysis includes time between failures and failure duration, however, this feature is taught by Loman (Col. 5, Ln. 14-16). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the system of Sheehan with the aforementioned feature from Loman with the motivation of having a fault resolution means (Loman: Col. 10-14) to detect faults and failures within the system of Sheehan.

Response to Arguments

10. Applicants' arguments that the applied references do not teach an asthmatic condition have been considered but are moot in view of the new grounds of rejection over the Finkelstein patent reference.

Applicants' arguments that the applied prior art references do not teach a sampling strategy are not persuasive. The Office relies on the Filangeri patent reference to teach a sampling strategy because it teaches a device that has the capability to collect data samples at a certain stated rate and store a certain amount of data collected over a given amount of time. The Office takes the position that this is a sampling strategy or plan in Filangeri because it is an

obvious design choice in that one of ordinary skill in the art applying the teachings of Filangeri could modify the rate at which the samples are taken or could modify the volume of data that is stored and/or modify the amount of time that the data is collected and/or stored for. Therefore, even though there is no mention in Filangeri of making choices or involving a plan, it is inherent that one of ordinary skill in the art would appreciate that this sampling strategy could be modified to meet the needs of a particular situation.

Applicants' arguments, against the 35 U.S.C. 101 rejections, with respect to Claims 9-10, 14-20, 25-26 and 30 have been considered but are not persuasive. Contrary to the applicants' contention the phrase "at least one data analysis mechanism" is not sufficient to overcome the 35 U.S.C. 101 rejection because the "at least one data analysis mechanism" could include someone's mind which is used to carry out the data analysis performed in the steps of the claimed invention. As noted above, the Office recommends that the applicants amend the claims so that a device (e.g. a computer) that carries out the claimed method is proactively recited in the body of the claim(s). In order to overcome this rejection, the Office recommends amending the claims so that they recite a device (e.g. a computer) which is used in carrying out the claimed method. The applicants are reminded, however, that any amendment(s) to the claim(s) must have support in the specification as it was originally filed. Therefore the amendment to Claim 9 filed on September 29, 2009 does not resolve this rejection.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. If any attempt to reach the examiner by telephone is unsuccessful, the examiner's supervisor, Jerry O'Connor, can be reached at (571) 272-6787. The fax telephone numbers for this group are either (571) 273-8300 or (703) 872-9326 (for official communications including After Final communications labeled "Box AF").

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vivek Koppikar, whose telephone number is (571) 272-5109. The examiner can normally be reached from Monday to Friday between 8 AM and 4:30 PM.

Another resource that is available to applicants is the Patent Application Information Retrieval (PAIR). Information regarding the status of an application can be obtained from the (PAIR) system. Status information for published applications may be obtained from

either Private PAIR or Public PAX. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please feel free to contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sincerely,

Vivek D Koppikar /VDK/

Primary Examiner, Art Unit 3686

11/17/2009